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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/063,227	04/20/98	CASAS-BEJAR	F-7109

QM32/1010

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EXAMINER  
THISSELL, J

ART UNIT	PAPER NUMBER
3763	19

DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/063,227

Applicant(s)

Casas-Bejar et al.

Examiner

Jeremy Thissell

Group Art Unit

3763



☒ Responsive to communication(s) filed on Jun 21, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 13-19, 24, 27, 29, 33, 34, and 36-44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 13-19, 24, 27, 29, 33, 34, and 36-44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 14, 15

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 38 and 44 are objected to because of the following informalities:

“Dexamethoasone” is misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 13-19, 24, 27, 29, 33, 34, 36-39, 41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chait '555 in view of Stokes (US Pat No. 4,711,251) and Fearnot et al '629.

Chait teaches a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. Chait lacks a layer with anti-inflammatory agent in it.

Stokes teaches an elongate body-inserted member with a drug imbedded in an outer non-porous silicone layer as claimed (col. 4, lines 24-28). Stokes also teaches that this drug can be an anti-inflammatory agent, anti-thrombotic agent, or combination of the two (col. 1, lines 65-67).

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It would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Stokes, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Fearnot also teaches a catheter (col. 6, line 25) with a drug imbedded in a non-porous layer 18, the drug specifically disclosed as dexamethasone (col. 8, line 66) in it. Fearnot also teaches that the catheter can have heparin embedded in it (col. 8, line 49). Since Stokes discloses the drugs so broadly, it would have been obvious to one of ordinary skill in the art to choose an appropriate anti-inflammatory and/or anti-thrombotic agent as taught by Fearnot for the intended use.

Fearnot teaches that the layers preferably contain in the range of about 0.5 to 2.0 mg/cm<sup>2</sup> of each heparin and dexamethasone, for a total of 1 to 4 mg/cm<sup>2</sup> of bioactive material (heparin and dexamethasone). At the top of page 12 of applicant's own specification it is disclosed that "Generally it is believed however, that less than about 1 mg of an anti-inflammatory agent per square centimeter of surface area of a polymer-contacting surface can be used to produce the advantageous results described herein. The ranges taught by Fearnot are consistent with applicant's own, therefore it would have been obvious to form the bioactive layers with the claimed weight percentages since it appears as though the same amounts of the bioactive materials are deemed to be suitable for this purpose by those skilled in the art.

The methods claimed in claims 27 and 29 claim only the step of inserting the catheter, which is clearly taught by Chait. The structure claimed in claims 27 and 29 is anticipated by the combination of Chait, Stokes, and Fearnot as discussed supra.

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The methods claimed in claims 33 and 34 claim simply that the catheter with the structure as claimed is assembled. The claims do not claim any specifics about the assembly. Clearly, it would have been obvious to one of ordinary skill in the art that the components of Chait must be put together in order to have the structure shown.

4. Claims 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chait '555 in view of Stokes (US Pat No. 4,711,251) and Fearnot et al '629 as applied to claims 13 and 29 above, and further in view of Hendriks et al (5,811,151).

Chait as modified by Stokes and Fearnot teaches all the claimed subject matter of claims 40 and 42 except for the anti-inflammatory agent being covalently bonded to the polymer surface. Hendriks teaches a catheter (col. 4, line 8), having an anti-inflammatory agent (col. 4, lines 23-24), wherein the agent is covalently bonded to the surface of the catheter (col. 4, line line 33-35).

It would have been obvious to one of ordinary skill in the art to use the covalent bonding as taught by Hendriks to embed the anti-inflammatory agent of Chait as modified by Stokes and Fearnot into layer 18 of Fearnot.

### ***Response to Arguments***

5. Applicant's arguments filed 21 June 2000 have been fully considered but they are not persuasive. Applicant presents no substantial arguments other than to say that the prior art does not

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teach the claimed subject matter. The examiner has addressed the claimed subject matter (in the claims as amended) in the rejection above.

***Conclusion***


6. This action is being made non-final in response to applicant's request for CPA and the pre-amendment filed therewith.


***Contacts***

Any inquiry concerning this communication should be directed to Jeremy Thissell at (703) 305-5261, or to Supervisory Patent Examiner Richard Seidel (703) 305-3009.

Jeremy Thissell

Patent Examiner

JT   
October 3, 2000

  
RICHARD SEIDEL  
SPE 3763